

REMARKS

Thirty-two (32) claims (Claims 1, 2, 4-17, 19-22, 40, and 42-53) remain pending in this application through this Amendment. New dependent Claims 52 and 53 have been added and Claims 1, 2, 4-12, 14-16, 19-22 and 40 have been amended to more clearly define the present invention. No new matter is added. As explained in more detail below, Applicant submits that the application is in condition for allowance and respectfully requests such action.

Rejection of Claims 1, 2, 4-14, 40, 42, and 44-53 under 35 USC §103(a) – Patel et. al. in view of Patel in further view of Kearns

Claims 1, 2, 4-14, 40, 42, and 44-53 stand rejected under 35 USC §103(a) as obvious in light of US Patent No. 6,158,862 to *Patel et al.*, in view of US Patent No. 5,252,262 to *Patel*, and in further view of US Patent No. 5,074,942 to *Kearns et al.*

The Patel '262 Patent

The Patel '262 patent relates to a method of attaching a separate haptic to an optic (see the title and abstract thereof). This patent recognizes the normal approach in the prior art of making the haptic and the optic of different materials and then attaching the haptic to the optic. Indeed, the Patel '262 patent is primarily directed to a way of making a reliable mechanical connection between these two different parts made from different materials. This patent is typical of the prior art discussed in the background portion of the present application. Nothing in the Patel '262 patent teaches or suggests the present invention of a unitary structure of homogenous material having a polyimide coating in the haptic region to increase fibrosis with the surrounding eye tissue.

The Kearns '942 Patent

The Kearns '942 patent discloses a "monolithic" intraocular lens having the optic and the haptics composed of the same basic material, but with the haptic having a colorant added thereto in order to improve the visibility of the haptic for the surgeon. The Kearns '942 patent does not discuss the problem of how to promote fibrosis in such a haptic in order to securely attach the lens to the eye, nor any solution to that problem. Additionally, the '942 patent fails to teach or suggest a polyimide coating on the haptic. In contrast, the present invention relates to a substantially homogenous unitary structure

with a polyimide coating in the haptic region that does not require the bonding as recited in the '942 patent.

The Patel '862 Patent

The Patel '862 patent discloses an intraocular lens that includes an optic portion and what appears to be an integral pair of extending haptic portions. This patent is primarily concerned with reducing unwanted optical effects (e.g., halos) in multi-focal lens. To minimize the unwanted optical effects, the Patel '862 patent discloses the use of a colorant or dye to filter out light near the ultraviolet range or near a particular wavelength range. The Patel '862 patent is not directed to, and does not disclose, how best to make an intraocular lens to ensure good attachment to the eye while minimizing manufacturing expense. Since the Patel '862 patent is directed to solving a different problem, it is not surprising that it does not disclose or suggest the use of a polyimide coating to improve attachment/bonding of the lens to the eye tissue.

The Invention As Claimed

In contrast to the above-cited references, the present invention is directed to a technology for utilizing a single material to make both the optic and the haptic, while still providing the optical and mechanical advantages that are attendant to using separate materials for the optic and the haptic. In particular, the present invention allows for the promotion of fibrosis to facilitate secure attachment of the haptic to the eye, while still utilizing a material for the optic with appropriate optical qualities. To this end, the invention as claimed in the claims is an intraocular lens having a unitary structure of homogenous, biologically inert material for both the optic and the haptic, and wherein a portion of the haptic is coated with polyimide to increase fibrosis with the surrounding tissue. Thus, the cost of manufacturing the lens can be controlled, while still providing the excellent attachment characteristics normally associated with the so-called "composite" intraocular lens type (optic and haptic made of different basic materials, but fastened together). For example, amended Claim 1 of the present application claims a unitary structure comprising a substantially homogeneous biologically inert material and including an optic portion and a haptic portion, with both the optic and haptic portions comprising the same biologically inert material, and at least one portion of the haptic portion is coated with polyimide to promote fibrosis between the haptic portion and the eye tissue to which the haptic portion is to be connected. This is nowhere found in the prior art, as will be discussed below.

The present invention as claimed is nowhere to be found in the prior art. Certainly none of the individual references of record disclose or suggest the claimed invention. Moreover, there is no suggested combination of references that would render the claims unpatentable. It is particularly noteworthy that none of the 3 references cited by the Examiner is even addressed to the same problem as the present application, let alone suggesting the same solution. Simply put, there is no recognition of this problem in these references, nor is there any disclosure or suggestion of this solution (as claimed) to the problem. It is respectfully submitted that the cited references do not individually or collectively disclose or suggest the invention as presently claimed.

The Examiner has pointed to no disclosure in these 3 patents or in any of the other art of record that would suggest making the combinations relied on by the Examiner in rejecting the claims previously. It appears that the only motivation for the combinations comes from the applicant's own disclosure, which of course amounts to improper hindsight reconstruction of the claimed invention, as explained further in the next paragraph.

One of skill in the art would not have been motivated to combine a unitary lens composed of biologically inert materials with a coating of polyimide to increase fibrosis. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The prior art fails to disclose suggest or expect a reasonable likelihood of success of a unitary structure composed of biologically inert material having a coating that would promote fibrosis around the haptic region. Therefore, holding such an assumption against the Applicant would be based upon impermissible hindsight.

Applicant further respectfully disagrees with the Examiner that the fibrosis promoting effect is inherent in a polyimide coating disclosed the '262 patent. As "[t]hat which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." *In re Spormann*, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966). In fact, the '262 patent teaches away from a unitary homogenous lens having a polyimide coating as it discloses a lens having an optic laser-welded to the haptics. See Column 4 of the Patel '262 patent. Because the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure, the present invention is not

rendered obvious by the cited references. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

For the foregoing reasons, Applicant believes Claims 1, 2, 4-14, 40, 42, and 44-53 are not obvious under US Patent No. 6,158,862 to *Patel et al.* in view of US Patent No. 5,252,262 to *Patel* in further view of US Patent No. 5,074,942 to *Kearns et al.*

Applicant, therefore, respectfully requests that this rejection be withdrawn.

Rejection of Claims 15-17, 19-22, and 43 under 35 USC §103(a) – Patel et al. in view of Patel and Kearns in further view of Cumming

Claims 15-17, 19-22, and 43 stand rejected under 35 USC §103(a) as being obvious under US Patent No. 6,158,862 to *Patel et al.* in view of US Patent No. 5,074,942 to *Kearns et al.* and US Patent No. 5,252,262 to *Patel* as applied to Claims 1, 2, 4-14, 40, 42, and 44-53 in further view of US Patent No. 5,047,051 to *Cumming*.

As discussed above, neither the '862 nor the 262 patent disclose or suggest a unitary lens having a polyimide coating to increase fibrosis. The '051 patent discloses an intraocular lens with an anchor plate. More specifically, the '051 patent discloses a lens having a soft deformable intraocular lens having a rigid haptic anchor plate. See Col. 2, ll. 13-15. The '051 patent fails to disclose or suggest, alone or in conjunction with the remaining asserted prior art, producing a unitary homogenous structure made of biologically inert materials coated with polyimide to increase fibrosis.

For the foregoing reasons, the Applicant believes Claims 15-17, 19-22, and 43 are not obvious under US Patent No. 6,158,862 to *Patel et al.* in view of US Patent No. 5,074,942 to *Kearns et al.* and US Patent No. 5,252,262 to *Patel* as applied to Claims 1, 2, 4-14, 40, 42, and 44-53 in further view of US Patent No. 5,047,051 to *Cumming*.

The Applicant, therefore, respectfully requests that this rejection be withdrawn.

Rejection of Claims 1, 2, 5, 7-14, 20, 22, 40, 42, and 44-53 under 35 USC §103(a) – Kearns in view of Patel

Claims 1, 2, 5, 7-14, 20, 22, 40, 42, and 44-53 stand rejected under 35 USC §103(a) as being obvious under US Patent No. 5,074,942 to *Kearns et al.* in view of and US Patent No. 5,252,262 to *Patel*.

The Examiner asserts the '942 patent discloses a lens in which the "lens and haptic have the same composition." As previously stated, the Patel '942 patent is

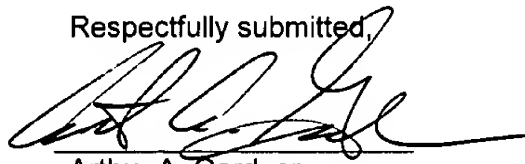
directed at "bonding" the haptics to the optic using a laser, rather than producing a one-piece unitary structure. The present invention does not claim a lens that only consists of a haptic region and optic having the same composition, but rather it claims such a lens that is a unitary structure with a portion being coated with polyimide.

For the forgoing reasons, the Applicant respectfully traverses the Examiners rejection of Claims 1, 2, 5, 7-14, 20, 22, 40, 42, and 44-53 under 35 USC §103(a) as being obvious under US Patent No. 5,074,942 to *Kearns et al.* in view of and US Patent No. 5,252,262 to *Patel*.

CONCLUSION

In view of the foregoing and in conclusion, Applicant submits that the 35 USC §103 rejections set forth in the Office Action have been overcome, and that the pending claims are not obvious in view of the cited art, either individually or in combination. Applicant respectfully requests reconsideration and withdrawal of the rejections set forth in the Office Action. Should the Examiner have any further reservations, the Examiner is respectfully invited to contact the undersigned to schedule a brief telephonic interview to bring the prosecution of this application to a conclusion.

Respectfully submitted,



Arthur A. Gardner
Reg. No. 33,887
(770) 984-2300

Gardner Groff, PC
600 Village Trace, Suite 300
Marietta, GA 30067